

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 09/647,475

Confirmation No.: 7111

Filed: August 20, 2001

For: COMPOSITE DEVICES INCORPORATING BIOLOGICAL MATERIAL AND METHODS

Remarks

The Office Action mailed September 21, 2005 has been received and reviewed. Claims 1-4, 11, 12, 14, 17, 19-22, 109, and 110 having been amended, claims 16, 18, 106, and 107 having been canceled, without prejudice, and claims 111-117 having been added, the pending claims are claims 1-15, 17, 19-24, 48, 100-105, and 108-117. Reconsideration and withdrawal of the rejections are respectfully requested.

Interview Summary

Applicants' Representative thanks Examiners Cheu and Le for extending the courtesy of conducting an interview with Dr. Michael C. Flickinger and Ann M. Muetting (Reg. No. 33, 977) on 21 December 2005. During the interview, numerous aspects of the invention and the cited art were discussed.

During the interview, Applicants stated that the styrene-butadiene copolymer Dow LATEX 233 referenced in column 8, line 35 of Foster et al. was believed to be an organic solvent based material. Although no product information was found on this specifically numbered material, Applicants found information on a styrene-butadiene copolymer material referred to as Dow LATEX "DL 233 NA." This material includes water according to the product information (submitted herewith); however, there is no information provided in the Dow LATEX DL 233 NA product literature whether this latex forms a porous or non-porous coating nor is there any information in the product literature regarding its effect on living cells, particularly when the living cells are mixed with the latex and during deposition (or printing) and film formation (coating or ink drying).

Thus, Applicants would like to clarify the record. However, if the Dow LATEX 233 did include water, there is still no teaching or suggestion of a composite biological device that includes a biostructure comprising at least one biological material as an integral imbedded component within the biostructure, wherein at least a portion of the biostructure comprises a nonporous latex-derived material and at least a portion of the biostructure comprises a porous

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latex-derived material having the at least one biological material imbedded therein, wherein the biological material is metabolically active or becomes metabolically active upon hydration.

It was further discussed that the nonporous latex-derived material of the biostructure is distinct from any substrate that could be used to support the biostructure. As described clearly in the specification, the biostructure can be self-supporting or disposed on a substrate (page 3, lines 10-11). Examples of suitable substrates are described at page 14, lines 3-15. Thus, the substrates referred to in the prior art (e.g., microtiter plate) are analogous to the optional substrate, not the nonporous latex-derived material of the biostructure.

The 35 U.S.C. §103 Rejections

The Examiner rejected claims 1-13, 15-24, 48, 100-104, 106-108, and 110 under 35 U.S.C. §103 as being unpatentable over Thiagarajan et al. (*European Federation of Biotechnology*, 1995; pg. 304) in view of Foster et al. (U.S. Patent No. 4,444,879). This rejection is respectfully traversed.

The Examiner rejected claims 14 and 105 as being unpatentable over Thiagarajan et al. in view of Foster et al., and further in view of Cantwell et al. (EP 0 288 203). This rejection is respectfully traversed.

The Examiner rejected claims 109 as being unpatentable over Thiagarajan et al. in view of Foster et al., and further in view of Martens et al. (*Analytica Chimica Acta*, 1994, pgs. 49-63). This rejection is respectfully traversed.

It is noted at page 4 of the Office Action that the Examiner refers to "the bioreactor of Villaverde et al." There is no other reference to Villaverde et al. throughout the Office Action. Clarification is requested.

Each independent claim recites a composite biological device that includes a biostructure comprising at least one biological material as an integral imbedded component within the biostructure, wherein at least a portion of the biostructure comprises a nonporous latex-derived

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material and at least a portion of the biostructure comprises a porous latex-derived material having the at least one biological material imbedded therein, wherein the biological material is metabolically active or becomes metabolically active upon hydration. None of the cited art teaches or suggests such a combination of materials, specifically the nonporous latex-derived material, porous latex-derived material, biological material imbedded in the porous latex-derived material. Applicants have discovered that such a combination provides a unique and advantageous composite material that can be used in a variety of applications, such as, for example, bioreactors, that allow for control of the placement of the biological material in a variety of microstructures.

As admitted by the Examiner at page 3 of the Office Action, Thiagarajan et al. do not teach a device that includes a nonporous latex-derived material (as recited in each independent claim). The Examiner further stated that he cited Foster et al. for a nonporous latex-derived material as a supporting substrate. As discussed above, the nonporous latex-derived material of the biostructure is distinct from any substrate that could be used to support the biostructure. As described clearly in the specification, the biostructure can be self-supporting or disposed on a substrate (page 3, lines 10-11). Examples of suitable substrates are described at page 14, lines 3-15. Thus, the substrates referred to in the prior art (e.g., microtiter plate) are analogous to the optional substrate, not the nonporous latex-derived material of the biostructure. In Applicants' claimed invention, the nonporous latex-derived material is a part of the biostructure. Claim 111 has been added to clarify that the device could include a substrate on which the biostructure is supported, but that the substrate is distinct from the nonporous latex-derived material of the biostructure.

Cantwell et al. and Martens et al. do not provide that which is missing from Applicants' invention. Accordingly, it is respectfully requested that these rejections be withdrawn.

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Summary

It is respectfully submitted that the pending claims 1-15, 17, 19-24, 48, 100-105, and 108-117 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23 day of January, 2006, at 4:35pm (Central Time).

By: Sue Dombroske
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